

Workgroup Report: Biomonitoring Study Design, Interpretation, and Communication—Lessons Learned and Path Forward

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Human biomonitoring investigations have provided data on a wide array of chemicals in blood and urine and in other tissues and fluids such as hair and human milk. These data have prompted questions such as *a)* What is the relationship between levels of environmental chemicals in humans and external exposures? *b)* What is the baseline or “background” level against which individual levels should be compared? and *c)* How can internal levels be used to draw conclusions about individual and/or population health? An interdisciplinary panel was convened for a 1-day workshop in November 2004 with the charge of focusing on three specific aspects of biomonitoring: characteristics of scientifically robust biomonitoring studies, interpretation of human biomonitoring data for potential risks to human health, and communication of results, uncertainties, and limitations of biomonitoring studies. In this report we describe the recommendations of the panel. *Key words:* biomonitoring, communication, design, human health, interpretation, specimen archiving. *Environ Health Perspect* 113:1615–1621 (2005). doi:10.1289/ehp.8197 available via <http://dx.doi.org/> [Online 6 July 2005]

Environmental health sciences focus on the relationship between exposures to environmental chemicals of concern and their relationship to health outcomes. The traditional method for assessing human exposures to environmental chemicals is to estimate, by empirical or modeling methods, the concentrations of chemicals of potential concern in environmental media (air, water, soil, food), and then combine this information with estimates of human exposure (e.g., estimates of daily consumption of tap water) to determine a dose. However, as analytic techniques have evolved, there has been an increasing focus on development and use of human biomonitoring (i.e., measurements of levels of environmental chemicals in human fluids such as blood, urine, or milk, and in tissues such as hair, nails, and fat) for evaluating exposure. These data have often supplemented or even supplanted estimates of exposure based on environmental measures.

Biomonitoring has been used for several decades for certain chemicals, such as for lead in blood and cotinine in urine. More recently, biomonitoring has provided data on levels of a much wider array of chemicals in various human fluids and tissues. In the United States, a systematic program of biomonitoring by the Centers for Disease Control and Prevention (CDC) has resulted in its National Report on Human Exposure to Environmental Chemicals (CDC 2003). This and other biomonitoring-based research have produced a substantial database on levels of environmental chemicals in humans. However, important questions

remain: What is the relationship between these internal levels and external exposures? What is the baseline or “background” level against which individual levels should be compared? And how can internal levels be used to draw conclusions about individual and/or population health?

Uncertainties related to the relationships of exposure with internal dose and of internal dose with potential for adverse health effects have been described by the CDC (CDC 2003) and others (LaKind et al. 2005; Sexton et al. 2003; Stokstad 2004). These uncertainties were also highlighted at a recent workshop on environmental chemicals in human milk (LaKind 2005), during which a multidisciplinary group addressed questions regarding interpretation of human milk biomonitoring data for both the health of the mother and the breastfeeding infant. Recognizing that individuals from an array of disciplines have been grappling with various aspects of biomonitoring and that these disparate disciplines bring different perspectives to the table, the Research Foundation for Health and Environmental Effects (RFHHE; a co-sponsor of the human milk biomonitoring workshop) convened an interdisciplinary panel for a 1-day workshop on 13 November 2004 with the charge of focusing on three specific aspects of biomonitoring: characteristics of scientifically robust biomonitoring studies, interpretation of human biomonitoring data for potential risks to human health, and communication of results, uncertainties, and limitations of biomonitoring studies. The RFHHE sought panel

members with expertise in medicine, toxicology, epidemiology, biostatistics, and risk assessment (the authors of this paper formed the workshop panel). During the workshop, the panel drew from the fields of medicine and occupational health, which have a long history of research on biomonitoring [National Institute for Occupational Safety and Health (NIOSH) 2004], as well as on the interpretation of the implications of biomonitoring results for individuals. In this report, we describe the recommendations reached during the workshop regarding biomonitoring study design, interpretation, and communication.

Recommendations of the Workshop Panel

Biomonitoring Study Design

The design of any scientific study depends on its goals and hypotheses. However, fundamental features that make for scientifically robust and credible studies exist. The panel focused on key research needs and recommendations for ensuring that the goals, hypotheses, and study design parameters are realistic, transparent, and scientifically robust.

Investigators need to gain not only approval but also acceptance for human studies. Biomonitoring studies involving human subjects “must be conducted in a way that protects subjects’ rights and well-being,” and must have the oversight of an institutional review board (IRB), as described by the Common

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